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NO. 0678 P. 1

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Pabst Patent Group LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, GA 30361

Telephone (404) 879-2150
Telefax (404) 879-2160

information@pabstpatent.com
www.pabstpatent.com

TELEFAX

Date: July 6, 2004

Total pages: 19

To: USPTO

Telephone: 703-308-0196

Telefax: 703-872-9306

From: Patrea L. Pabst

Telephone: 404-879-2151

Telefax: 404-879-2160

Our Docket No. ICI 102

Client/Matter No. 078230/00027

Your Docket No.

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MESSAGE:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stefan Dietmar Anker and Andres Justin Stewart Coats

Serial No.: 09/807,558

Art Unit: 1647

Filed: July 17, 2001

Examiner: Fozia M. Hamud

For: *METHODS OF TREATMENT*

PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	09/807,558
	Filing Date	July 17, 2001
	First Named Inventor	Stefan Dietmar
	Art Unit	1647
	Examiner Name	Fozia M. Hamud
Total Number of Pages in This Submission	Attorney Docket Number	ICI 102

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input checked="" type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks _____		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	Patricia L. Pabst, Esq., Reg. No. 31,284 Pabst Patent Group LLP 400 Colony Square, Suite 1200; 1201 Peachtree Street, N.E.; Atlanta, GA 30361	
Signature	_____	
Date	July 6, 2004	

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PTO/SB/17 (10-03)

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003, Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

(\$) 130.00

Complete if Known

Application Number	09/807,558
Filing Date	July 17, 2001
First Named Inventor	Stefan Dietmar
Examiner Name	Fozia M. Hamud
Art Unit	1647
Attorney Docket No.	ICI 102

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit AccountDeposit Account Number
Deposit Account Name

50-3129

Pabst Patent Group LLP

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
40	-40* =	X	
9	-9** =	X	
Multiple Dependent			

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 280	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

**or number previously paid, if greater. For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1480 130	1480 130	Petitions to the Commissioner	130
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (lines number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 130

SUBMITTED BY

Name (Print/Type) Patrea L. Pabst

Registration No. (Attorney/Agent)

31,264

(Complete if applicable)

Telephone (404) 879-2151

Signature

Date

July 6, 2004

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NO. 0678 P. 4

JUL 06 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stefan Dietmar Anker and Andres Justin Stewart Coats

OFFICIAL

Serial No.: 09/807,558

Art Unit: 1647

Filed: July 17, 2001

Examiner: Fozia M. Hamud

For: *METHODS OF TREATMENT*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

Sir:

Pursuant to Pursuant to 37 C.F.R. § 1.144, applicants petition the Group Director to review the restriction requirement set forth in the Office Action mailed on January 6, 2004, as maintained in the Office Action mailed on May 3, 2004. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

45048596_1

ICI 102
078230/00027

U.S.S.N. 09/807,558

Filed: July 17, 2001

PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**Remarks**

In the Office Action mailed January 6, 2004, the claims were divided into 16 groups. The claims, as pending, are attached as an Appendix for the convenience of the Group Director.

Claim 1 is directed to a method of treating weight loss due to underlying disease in a patient the method comprising administering to the patient an effective amount of an agent which reduces sympathetic nervous system activity.

Group I Claims 1-3, 19, 29-31, 35-36, 38-39, (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone.

Group II Claims 1-2, 5, 6, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 6, drawn to a method of administering to a patient a chymase inhibitor.

Group III Claims 1-2, 7, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 8, drawn to a method of administering to a patient a cathepsin inhibitor.

Group IV Claims 1-2, 9, 11, 13, 15, 19, 23, 29-31, 35-36, 38-39, 41 (in part) and claims 10, 12, 16 and 24, drawn to a method of administering to a patient a receptor blocker.

Group V Claims 1-2, 17, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 18, drawn to a method of administering to a patient a ganglion blocking agent.

Group VI Claims 1-2, 19, 21, 29-31, 35-36, 38-39, 41 (in part) and claim 20, drawn to a method of administering to a patient an opiate.

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PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

Group VII Claims 1-2, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 22, drawn to a method of administering to a patient a compound that inhibits the effect of scopolamine.

Group VIII Claims 1-2, 19, 25, 29-31, 35-36, 38-39, 41 (in part) and claim 26, drawn to a method of administering to a patient a xanthine oxidase inhibitor.

Group IX Claims 1-2, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 27, drawn to a method of administering to a patient an erythropoietin.

Group X Claims 1, 19, 29-31, 35-36, 41 (in part) and claim 14, drawn to a method of administering to a patient a receptor agonist.

Group XI Claims 38 and 39 (in part), drawn to a method of administering to a patient a digitalis alkaloid.

Group XII Claims 38 and 39 (in part), drawn to a method of administering to a patient a growth hormone.

Group XIII Claims 38 and 39 (in part), drawn to a method of administering to a patient an insulin like growth factor.

Group XIV Claims 38 and 39 (in part), drawn to a method of administering to a patient an endothelin antagonist.

Group XV Claims 38 and 39 (in part), drawn to a method of administering to a patient a TNF antagonist.

Group XVI Claims 28, 37, 40 and 46-47, drawn to a method of electrically stimulating a patient's muscles.

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ICI 102
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Filed: July 17, 2001

PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

Applicants provisionally elected Group I, Claims 1-3, 19, 29-31, 35-36, 38-39, (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone with traverse.

The Restriction Requirement is Improper.

The Examiner has applied PCT rules for Unity of Invention because this application is a 371 of PCT/GB99/03302. PCT Rule 13.2 deals with the requirement of unity of invention and defines the method for determining whether the requirement is satisfied. "Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features".

The independent claims in the present application are sufficiently linked as to form a single general inventive concept defined by claim 1. This inventive concept finds expression in common technical features which define the inventive contribution that the claims invention makes over the prior art- specifically to treat weight loss by administering an inhibitor of sympathetic nervous system activity. The Examiner has improperly limited the scope of the claimed invention to a single species defined as one of several compounds, listed in dependent claim 2. Even as to this single species, the reference cited by the Examiner, Mueller and Ayres, J. Clin. Invest. 65: 338-346 (1980), does not teach or suggest the use of propranolol for the treatment of cachexia, nor has the examiner provided a basis in fact and/or technical reasoning to reasonably support the determination that this allegedly inherent characteristic of propranolol

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necessarily flows from the teachings of Mueller and Ayres. *In Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int'f., 1990).

At most, the claims should have been divided into the following groups along with an election of species for the compound to reduce sympathetic nervous system activity.

Group I: claims 1-27, 29-31, 35 and 36 drawn to a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity.

Group II: claims 28, 37, 46 and 47 drawn to a method of treating weight loss by electrically stimulating the patient's muscles.

Group III: claims 38-40 drawn to a method of enhancing exercise performance.

Group IV: claim 41 drawn to a method of treating weight loss associated with a cardiovascular disorder.

The Claims meet the Unity of Invention Standards for Markush Practice

PCT Rule 13.2 also governs so called Markush practice. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present,

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PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the present application, the claims have the common property/ activity of decreasing sympathetic nervous system activity and are all recognized as being sympathetic nervous system blockers. These are known compounds with recognized activities and classification, although not for treating weight loss.

Division of Single Claims into Multiple Inventions is Improper

It is improper to divide a single claim such as claim 1 into a plurality of inventions as the Examiner has done. Proper practice would be to require an election of species for search purposes. It is understood that once a species is determined to be free of prior art, the remaining species will also be searched.

The proper restriction in the instant application would be to divide the claims based on the method of treatment as described above and require an election of species for the compound to be administered.

Claims 1-27, 29-31, 35 and 36 all clearly define essential characteristics of the single embodiment of the invention that being *a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity*. The examiner has divided the generic claims into different groups based on description in the specification of what molecules can be used, *even in the complete absence of any such limitations in the claims!*

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PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

There is **no limitation** in the independent claim to specific compounds to inhibit sympathetic nervous system activity. Clearly, the examiner is trying to impose limitations not present in the claims through the vehicle of a restriction requirement, without examination under 35 U.S.C. § 102, 103 or 112.

It is stated in the MPEP that, "where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are but different definitions of the same disclosed subject matter, varying in breadth or scope of definition." (MPEP 806.03)

The case has already been pending for three years. In that time the Examiner has issued two restriction requirements and a letter requesting clarification- prosecution has been delayed.

The restriction requirement, by creating separate inventions out of the generic claims, makes it impossible to examine the claims in their entirety, and forces the applicants to restrict it to a single species. The examiner has no legal authority to require applicants to restrict a generic claim to a single species, absent prior art or lack of enablement.

Summary

The current restriction imposed on the claims of the present invention is improper. This restriction is inconsistent with the guidelines for restriction practice delineated by the MPEP and PCT rules. Upholding this restriction requirement would be to allow the examiner to impose limitations on the claims *which are not now present*.

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078230/00027

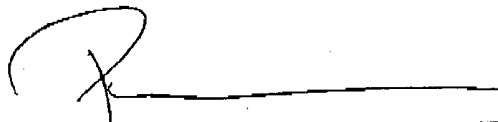
U.S.S.N. 09/807,558

Filed: July 17, 2001

PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

Favorable consideration of this petition is earnestly solicited.

Respectfully submitted,



Parrea L. Pabst
Reg. No. 31,284

Date: July 6, 2004

PABST PATENT GROUP LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, Georgia 30361
(404) 879-2151
(404) 879-2160 (Facsimile)

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I hereby certify that this Petition for Reconsideration of Restriction Requirement, and any documents referred to as attached therein are being facsimile transmitted on the date shown below, to the Commissioner for Patents, U.S. Patent and Trademark Office, Alexandria, VA 22313-1450.



Brian Adams

Date: July 6, 2004

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078230/00027